Exactech® Gibralt® Rod-to-Rod Cross Connectors
Special 510(k) – 510(k) Summary of Safety and Effectiveness

APR 1 1 2014

Sponsor: Exactech, Inc.
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FDA Establishment Number 1038671

Contact: Patrick Hughes
Senior Regulatory Affairs Specialist

Date: March 12, 2014

Trade of Proprietary or Model Name(s):
Exactech® Gibralt® Rod-to-Rod Cross Connectors

Common Name:
Spinal Fixation System

Classification Name:

- 21 CFR 888.3050 - Spinal interlaminal fixation orthosis, Class II, Product Code: KWP - appliance, fixation, spinal interlaminal

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or Proprietary Model Name	Manufacturer
K110197	Gibralt Spinal System	Exactech, Inc

Indications for Use:
When intended to promote fusion of the cervical spine, and the thoracic spine, (C3-T3), the Gibralt Spinal System is indicated for the following: DDD (neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, spinal stenosis, fracture, dislocation, failed previous fusion and/or tumors. The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C3-T3) spine.

The use of polyaxial screws is limited to placement in T1-T3 in treating thoracic conditions only. Polyaxial screws are not intended to be placed in the cervical spine.

This system can be used independently or in conjunction with Exactech 5.5mm or 6.0mm rod-based Thoraco-Lumbar Pedicle Screw Systems.

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Device Description:
Gibralt Rod-to-Rod Cross Connectors represent a line extension to the Gibralt Spinal System. The Gibralt Spinal System is a top-loading spinal fixation system comprising a range of polyaxial screws, rods, hooks, and various connectors. Gibralt Spinal System devices are used by surgeons to immobilize and stabilize spinal segments as an adjunct to fusion of the cervical and/or upper thoracic spine.

As with other Gibralt Spinal System cross-connectors, Gibralt Rod-to-Rod Cross Connectors are designed to increase the rigidity of Gibralt Spinal System constructs. Gibralt Rod-to-Rod Cross Connectors can be used at any point along a Gibralt Spinal System rod, where previous cross connectors can only be used at connection points in a system construct. This line extension is proposed to provide surgeons with additional options for stabilizing and/or immobilizing spinal segments as an adjunct to spinal fusion.

Like all Gibralt Spinal System components, the proposed Gibralt Rod-to-Rod Cross Connectors are manufactured from titanium alloy per ASTM F136. All implantable Gibralt Spinal System components are provided non-sterile, and must be steam sterilized by the hospital prior to use.

Bench Testing:
Mechanical properties for Gibralt Rod-to-Rod Cross Connectors were assessed per ASTM F1717-13:

- Static compression bending
- Dynamic compression bend strength

Substantial Equivalence Conclusion:
Detailed device comparison, bench testing, and engineering studies included or referenced in this submission demonstrate the proposed Gibralt Rod-to-Rod Cross Connectors are substantially equivalent to cleared predicate Gibralt Spinal System devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 11, 2014

Exactech, Incorporated
Mr. Patrick Hughes
Senior Regulatory Affairs Specialist
2320 N.W. 66th Court
Gainesville, Florida 32653

Re: K140645
Trade/Device Name: Exactech® Gibralt® Rod-to-Rod Cross Connectors
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP
Dated: March 12, 2014
Received: March 13, 2014

Dear Mr. Hughes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K140645

Device Name
Gibralt Spinal System Rod-to-Rod Connectors

Indications for Use *(Describe)*
When intended to promote fusion of the cervical spine, and the thoracic spine, (C3-T3), the Gibralt Spinal System is indicated for the following: DDD (neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, spinal stenosis, fracture, dislocation, failed previous fusion and/or tumors. The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C3-T3) spine.
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Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

James P. Bertram -S
2014.04.10 16:25:37 -04'00'

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